

## **REMARKS**

Claims 1-14 and 16-21 are all of the pending claims, with claims 1, 18, and 20 being written in independent form.

### **I. Claim Rejections on Prior Art Grounds:**

The Examiner rejects:

1. claims 1, 11 and 18-20 under 35 USC §103(a) as being obvious over US 5,044,372 to Anhäuser et al. (“Anhäuser”) in view of US 4,765,986 to Liedtke (“Liedtke”) and US 4,450,845 to Engel (“Engel”);
2. claims 2-4, 17 and 21 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of US 4,887,611 to Rüdiger et al. (“Rüdiger”);
3. claim 5 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of US 4,450,844 to Quisno (“Quisno”);
4. claim 6 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of US RE37,934 to Hoffmann (“Hoffmann”);
5. claim 7 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of US 4,543,964 to Breneman (“Breneman”);
6. claim 8 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of NL 8701577 to van der Bend (“van der Bend”);
7. claims 9, 12 and 13 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engel, and further in view of US 4,472,507 to Pluim, Jr. (“Pluim”);
8. claims 10 and 14 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke, Engel and Pluim, and further in view of US 4,158,359 to Kurokawa et al. (“Kurokawa”); and
9. claim 16 under 35 USC §103(a) as being obvious over Anhäuser in view of Liedtke and Engle, and further in view of US 4,809,707 to Kraft et al. (“Kraft”).

Applicant respectfully traverses all of these rejections in view of the following remarks.

## II. Independent Claim 1:

Independent claim 1 recites that each test chamber includes (among other things):

1. a “*frame-shaped foam plastic layer*” secured on top of and embracing the support element, and defining at least some sidewalls of the test chamber that directly confront each other;
2. a “*first layer of adhesive*” provided on the outwardly directed side of the frame-shaped foam plastic layer; and
3. a “*second layer of adhesive*” interposed between the frame-shaped foam plastic layer and the support element.

By way of example only, and with reference to Fig. 2, the frame-shaped foam plastic layer 25 is secured on top of the support element 17. As shown, the frame-shaped foam plastic layer 25 defines at least some sidewalls of the test chamber 31 that directly confront each other. For example, the left sidewall faces the right sidewall without any other elements intervening between these two sidewalls. A first layer of adhesive 26 is provided on the outer side (or upper side) of the frame-shaped foam plastic layer 25. And a second layer of adhesive 22/23 is interposed between the frame-shaped foam plastic layer 25 and the support element 17. At least these features (as recited in independent claim 1), in combination with the other features recited in independent claim 1, are not taught or suggested by the prior art relied upon by the Examiner.

In rejecting claim 1, the Examiner recognizes that the primary reference to Anhäuser is not relevant to several features of claim 1. Therefore, the Examiner looks to the secondary references of Liedtke and Engel to teach the missing features. In so doing, the Examiner relies upon two successive modification of Anhäuser. Applicant discusses each of the alleged modifications (and its deficiency) separately below.

### A. The First Modification:

With reference to Fig. 1 of Anhäuser, the Examiner recognizes that Anhäuser’s locking ring 15 is not “*foam plastic*,” and that the outwardly directed side of the locking ring 15 is not provided with a “*first layer of adhesive*,” as claimed.<sup>1</sup> Therefore, the Examiner relies upon a modification that involves dispensing with Anhäuser’s locking ring 15 in favor of Liedtke’s

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<sup>1</sup> Office Action, p. 3, lines 1-4.

foam ring 10 and adhesive layer 11 (see Fig. 4).<sup>2</sup> This rejection position is not convincing for several reasons.

The Articulated Motivation is in Error

The Examiner reasons that the alleged modification would have been obvious to “*provide direct adhesion of the frame to skin to prevent leakage of the testing material from the test site.*”<sup>3</sup> However, Liedtke’s foam ring 10 does **not** have anything whatsoever to do with direct adhesion to skin. With reference to 4 of Liedtke, it is the adhesive layer 11 (and no other element) that adheres the device to the skin. Indeed, Liedtke’s straightforward disclosure indicates that the adhesive layer 11 is used for attaching the plaster to the skin.<sup>4</sup> Certainly then, the Examiner has not provided any valid reason that would have prompted an artisan to incorporate Liedtke’s foam ring 10 into Anhäuser’s device. In this regard, the alleged modification appears to be based upon an impermissible hindsight of Applicant’s disclosure.

Turning to the next point, Anhäuser’s device (without any modification) ***already prevents leakage of material from the test site.*** Indeed, as background, Anhäuser expressly indicates that it is desirable to provide a plaster that is “*watertight,*” but that watertightness cannot be realized using conventional structures.<sup>5</sup> Anhäuser overcomes the shortcomings associated with conventional structures (including the inability to provide watertightness) by providing a carrier film 12 that is fabricated from a highly elastic polymer material that is “*tight for liquid water.*”<sup>6</sup> As shown in Fig. 1, the carrier film 12 supports a contact adhesive layer 13 that (upon application) adheres together the carrier film 12 and the test area ... resulting in a fluid tight enclosure within the locking ring 15.<sup>7</sup> Accordingly, those skilled in the art would not have been prompted to implement the alleged modification because doing so would have served no apparent purpose.

The Rejection Rationale is Incorrect

The Examiner’s characterization of the alleged modification as a ***substitution of one known element for another*** is incorrect. This is because the modification involves dispensing

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<sup>2</sup> Office Action, p. 3, lines 14-20.

<sup>3</sup> *Id.*

<sup>4</sup> See Liedtke, col. 5, lines 48-49.

<sup>5</sup> Anhäuser, col. 1, lines 43-50.

<sup>6</sup> Anhäuser, col. 1, lines 55-57.

<sup>7</sup> See Anhäuser, col. 3, lines 12-21.

with only one element from Anhäuser (*i.e.*, the locking ring 15) in favor of two elements from Liedtke (*i.e.*, the foam ring 10 + the adhesive layer 11). That is, the alleged modification includes more elements than Anhäuser's disclosed device. This is the hallmark of ***combining prior art elements***, but not an indicia of a simple substitution of one part for another.

Applicant's position in this regard is consistent with the numerous and varied examples provided in the examination guidelines for determining obviousness under 35 USC §103 in view of the Supreme Court decision in KSR International Co. v. Teleflex Inc.<sup>8</sup>

The rationale to support a combination of prior art elements requires satisfaction of a four part test. In the situation at hand, however, at least the first two parts of the four part test are ***not satisfied***.

Specifically, the first part of the test requires that the prior art included each element claimed, with the ***only difference*** between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference.

In the situation at hand, the Examiner attempts to compare Liedtke's foam ring 10 to the claimed frame-shaped foam plastic layer. As shown in Fig. 4 of Liedtke, however, the foam ring 10 is ***not "secured on top of"*** the synthetic material disk 1, as claimed. Instead, the foam ring 10 surrounds only the perimeter of the synthetic material disk 1. Further, the foam ring 10 does ***not*** define "*at least some sidewalls of the test chamber that directly confront each other,*" as claimed. Indeed, the synthetic material disk 1 (positioned in foam ring 10) necessarily prevents any sidewalls of the foam ring 10 from directly confronting each other. These structural differences are significant because they are in addition to the lack of actual combination of the claim elements in a single reference (which is the ***only difference*** permitted by the rationale).

The second part of the test requires that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.

As currently understood, the alleged modification would include Liedtke's foam ring 10 mounted on Anhäuser's receiving device 14 such that the foam ring 10 at least partially covers the receiving device 14, and is fixed to the adhesive layer 13 (*i.e.*, forming a "stacked structure" similar to the locking ring 15 depicted in Fig. 1 of Anhäuser). Here, the foam ring 10 would

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<sup>8</sup> See, Federal Register, vol. 72, no. 195, p. 57526-57535, October 10, 2007.

function to partially cover the receiving device 14 to prevent unintentional migration of material from the receiving device 14.<sup>9</sup> By virtue of this arrangement, the foam ring 10 would secure the receiving device 14 in position, and prevent it from falling from the modified device. This functionality is simply not present in Liedtke's device, where the foam ring 10 surrounds only the perimeter of the synthetic material disk 1, but it does not cover the outwardly facing side of the disk 1. Liedtke's arrangement is not incidental because an express object of Liedtke is to provide improved mechanical separation between the carrier substance (or disk 1) and the housing.<sup>10</sup> In short, the foam ring 10 would function differently in the alleged combination than it does in Liedtke.

**B. The Second Modification:**

The Examiner recognizes that the initial modification does not include a "*second layer of adhesive*," as claimed.<sup>11</sup> Therefore, the Examiner relies upon a second modification that involves incorporating a second layer of adhesive (as taught by Engel) on the base/support contacting side of the foam ring 10, which would be interposed between the foam ring 10 and the receiving device 14.<sup>12</sup> This rejection position is not convincing.

The Articulated Motivation is in Error

The Examiner reasons that the second modification would have been obvious "*to provide attachment between the frame layer and the support layer*." However, according to the Examiner's initial modification, the foam ring 10 and the receiving device 14 would already be fixed together via the adhesive layer 13 provided on the carrier film 12. That is, without any further modification, both the foam ring 10 and the receiving device 14 would be fixed to the adhesive layer 13, and therefore these elements would be necessarily fixed together. Anhäuser's disclosure is straightforward in this regard.<sup>13</sup> Accordingly, those skilled in the art would not have been prompted to implement the alleged second modification because doing so would have served no apparent purpose.

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<sup>9</sup> See Anhäuser, col. 3, lines 12-21.

<sup>10</sup> Liedtke, col. 2, line 67 – col. 3, line 2.

<sup>11</sup> Office Action, p. 3, lines 1-4.

<sup>12</sup> Office Action, p. 3, line 20 – p. 4, line 2.

<sup>13</sup> See Anhäuser, col. 4, lines 4-7.

Furthermore, the Examiner has not offered any explanation as to why such an attachment feature would have been desirable in the first place. In fact, the only apparent result from the second modification (*i.e.*, the incorporation of an additional adhesive layer) would be to undesirably increase the thickness of the device and increase manufacturing effort/time. Without any apparent advantage, the second modification appears to be based upon an impermissible hindsight of Applicant's disclosure.

The Second Modification would be Inoperative

With reference to Fig. 2 of Engel (which is the embodiment relied upon by the Examiner), the layer 22 has an adhesive coating on both sides. Significantly, Engel teaches that the stickiness of the adhesive on the skin contacting side (or bottom side) is “*more aggressive*” than the stickiness of the adhesive on the lid contacting side (or upper side).<sup>14</sup> This relative stickiness is necessary to prevent the device from being removed from the skin each time the lid 25 is raised.<sup>15</sup>

If Engel's adhesive layer were incorporated (as alleged by the Examiner), then the adherence between the foam ring 10 and the carrier film 12 would be ***less than*** (1) the adherence between the foam ring 10 and the protective layer 16, and (2) the adherence between the foam ring 10 and the skin. Accordingly, the device would be destroyed (*i.e.*, the foam ring 10 would separate from the remainder of the device) when removing the protective layer 16 prior to applying the device to the skin, and when removing the device from the skin. Certainly then, those skilled in the art would not have been motivated to implement the second modification.

### **III. Independent Claims 18 and 20:**

Independent claims 18 and 20 are somewhat similar to claim 1. For example, claim 18 recites (among other things) (1) a frame-shaped “*foam plastic*” layer; (2) “*adhesive means*” provided on the frame-shaped foam plastic layer; and (3) a “*layer of adhesive*” interposed between the frame-shaped foam plastic layer and the support element. And claim 20 recites (among other things) (1) a frame-shaped “*foam plastic*” layer; (2) a first “*adhesive layer*” provided on the frame-shaped foam plastic layer; and (3) a second “*adhesive layer*” interposed

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<sup>14</sup> Engel, col. 3, line 68 – col. 4, line 6.

<sup>15</sup> *Id.*

between the frame-shaped foam plastic layer and the support element. Accordingly, Applicant believes that claims 18 and 20 are patentable for reasons analogous to those noted above with respect to claim 1.

### **CONCLUSION**

In view of the above, Applicant earnestly solicits reconsideration and allowance of all of the pending claims.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 50-4446 for any additional fees required under 37 CFR § 1.16 or under 37 CFR § 1.17; particularly, extension of time fees.

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